June 15, 2026

Zhongshan Sulenz Intelligent Technology Co., Ltd.
℅ Andrew Wang
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai, China

Re: K260335
Trade/Device Name: Electric Wheelchair (S500-6)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: June 1, 2026
Received: June 2, 2026

Dear Andrew Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260335

Please provide the device trade name(s).

Electric Wheelchair (S500-6)

Please provide your Indications for Use below.

The device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K260335

510(k) Summary

Prepared on: 2026-06-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zhongshan Sulenz Intelligent Technology Co., LTD
Applicant Address	One of 2F B Area, A4 building, No. 17 Shabian Road, Shabian Industrial Zone, Torch Development Zone, Zhongshan City, Guangdong Province, China Zhongshan China
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Correspondent Contact	Mr. Andrew Wang
Correspondent Contact Email	yuanju.wang@sungoglobal.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Electric Wheelchair (S500-6)
Common Name	Powered wheelchair
Classification Name	Wheelchair, Powered
Regulation Number	890.3860
Product Code(s)	ITI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220156	Electrically Powered Wheelchair	ITI

Device Description Summary

21 CFR 807.92(a)(4)

This product consists of frame, wheels, seat, armrest, lithium battery, motor and controller with a lightweight and compact design. The seat cushion is detachable. The armrest can be flipped backward, which is convenient for the elderly to move. Users can drive the wheelchair by themselves through the control device.

The wheelchair uses lithium batteries as its power source. The controller controls the drive left/right motor to realize the wheelchair forward, backward and turn functions.

The frame is made of aluminium alloy. The front wheels are driven wheels, which are used for the wheelchair's rotation, acceleration, and backward movement. The rotation of the front wheels is driven by the thrust generated by the rear wheels. The rear wheels are driving wheels, used to control speed and direction. The wheels are PU tires.

In use, the operator drives the rear wheel motor via a joystick to rotate the rear wheels.

The DC motor and braking system are fixed to the rear wheel.
The max loading of the device is 100 kg. Only for one person sit.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device is a motor-driven, and indoor transportation vehicle with the intended use to provide mobility to a disabled or an elderly person limited to a seated position.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device and predicate device are complying to the same ISO standards, ISO 7176-1, ISO 7176-2, ISO 7176-3, ISO 7176-4, ISO 7176-5, ISO 7176-6, ISO 7176-7, ISO 7176-8, ISO 7176-9, ISO 7176-10, ISO 7176-11, ISO 7176-13, ISO 7176-14, ISO 7176-15, ISO 7176-16/ ISO 16840-10, ISO 7176-21, ISO 7176-22, ISO 7176-25, and FDA guidance Submission for Power Wheelchair.
The proposed device performs in a similar manner to the predicate device. All these tests have corresponding requirements/ control criteria following above mentioned standards. And the test results show that the subject product is substantially equivalent to the predicate device in performance.
The performance testing demonstrates that the subject device is substantially equivalent to the predicate devices regarding Static ability (tipping angle), The Dynamic stability (Safe Gradient Maximum Gradient), Brake performance, Theoretical distance range, Dimension and weight, Maximum speed, Dimension of wheel Static, impact and fatigue strengths, Climatic tests, Obstacle-climbing ability, Dummy, friction of test surfaces, Power and control systems, Documentation and labeling, Resistance to ignition, Electromagnetic Compatibility and Electrical Safety, Batteries and chargers.
The non-clinical laboratory data support the safety and performance of the subject device and demonstrate that the subject device should perform as intended in the specified use conditions.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 7176-1: 2014, Wheelchairs - Part 1: Determination of static stability
ISO 7176-2: 2017, Wheelchairs - Part 2: Determination of dynamic stability of PoweredWheelchairs
ISO 7176-3: 2012, Wheelchairs - Part 3: Determination of effectiveness of brakes
ISO 7176-4, Third edition 2008-10-01, Wheelchairs - Part 4: Energy consumption of electricwheelchairs and wheelchairs for determination of theoretical distance range
ISO 7176-5, Second edition 2008-06-01, Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
ISO 7176-6: 2018, Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of Powered Wheelchairs
ISO 7176-7, Wheelchairs - Part 7: Measurement of seating and wheel dimensions
ISO 7176-8:2014,Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9:2009, Wheelchairs - Part 9: Climatic tests for PoweredWheelchairs
ISO 7176-10:2008, Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
ISO 7176-11:2012 Wheelchairs - Part 11: Test dummies.
ISO 7176-13, First edition 1989-08-01, Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
ISO 7176-14:2022, Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and wheelchairs - Requirements and test methods
ISO 7176-15:1996,Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
ISO 16840-10:2021 Wheelchair seating Part 10: Resistance to ignition of postural support devicesRequirements and test method.
ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and wheelchairs, and battery chargers
ISO 7176-25:2022 Wheelchairs - Part 25: Lead-acid batteries and chargers for powered wheelchairs Requirements and test methods
IEC 62133-2:2017/AMD1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Clinical tests: Not Applicable.

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, Electric Wheelchair, model(s): S500-6, is as safe, as effective, and performs as well as the legally marketed predicate device cleared under K220156.